

October 11, 2002

Joseph D. Ziegler, Acting Assistant Manager  
Office of Licensing and Regulatory Compliance  
U.S. Department of Energy  
Yucca Mountain Site Characterization Office  
P.O. Box 364629  
North Las Vegas, NV 89036-8629

SUBJECT: TOTAL SYSTEM PERFORMANCE ASSESSMENT AND INTEGRATION KEY  
TECHNICAL ISSUE AGREEMENTS

Dear Mr. Ziegler:

During a Technical Exchange and Management Meeting held on August 6-10, 2001, the U.S. Nuclear Regulatory Commission (NRC) and the U.S. Department of Energy (DOE) reached agreement on a number of issues within the Total System Performance Assessment and Integration (TSPAI) Key Technical Issue (KTI). By letter dated May 9, 2002, DOE submitted information to address TSPAI Agreements 3.38, 3.39, 3.40, 3.41, 4.01, and four parts of General Agreement 1.01 (Items 56, 78, 96, and 120). The information was provided in a document entitled "Guidelines for Developing and Documenting Alternative Conceptual Models, Model Abstractions, and Parameter Uncertainty in the Total System Performance Assessment for the License Application" (herein referred to as the "Guidelines"). TSPAI Agreements 3.39, 3.41, and 4.01 involve information that is not included in the Guidelines. In its May 9, 2002, letter, DOE requested that NRC consider TSPAI Agreements 3.39, 3.40, and 4.01 as complete based on the approach outlined in the Guidelines. The NRC staff has reviewed this information as it relates to the agreements and the results of the staff's review are enclosed.

TSPAI Agreements 3.38 and 3.40 address the approach that DOE will use to develop the information that will support the potential license application and TSPAI Agreements 3.39, 3.41, and 4.01 address directly the information that the NRC staff believes is necessary to conduct a detailed review of that potential license application. In summary, additional information is needed for TSPAI Agreements 3.38, 3.39, 3.41, and 4.01. TSPAI Agreement 3.40 is listed as "complete." For TSPAI Agreement 3.38, additional information is needed for the NRC staff to understand DOE's approach when relying on technical judgement in a complex system-model such as the total system performance assessment (TSPA). For TSPAI Agreements 3.39, 3.41, and 4.01, the NRC staff has decided that it is premature to characterize these agreements as complete solely on the basis of the Guidelines provided by DOE. It is premature because: (1) there is no objective evidence of the successful implementation of the Guidelines and (2) the Guidelines do not embody the same gravity as do quality assurance procedural requirements, where audits are conducted to evaluate adherence to the procedures. In addition, for TSPAI Agreements 3.41 and 4.01, the NRC staff has identified, based on the content of the Guidelines, additional information that is needed. For TSPAI Agreement 3.40, the process outlined by DOE provides an additional level of detail to that found in the governing procedure. The program improvements outlined in the Guidelines address the NRC staff concerns and satisfy the intent of the agreement.

J. Ziegler

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If you have any questions regarding this letter, please contact Mr. Daniel Rom of my staff. He can be reached at (301) 415-6704.

Sincerely,

**/RA/**

Janet Schlueter, Chief  
High-Level Waste Branch  
Division of Waste Management  
Office of Nuclear Material Safety  
and Safeguards

Enclosure: As stated

cc: See attached distribution list

J. Ziegler

-2-

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Letter to J. Ziegler from J. Schlueter dated \_\_\_\_\_

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C. Meyers, Moapa Paiute Indian Tribe  
V. Miller, Fort Independence Indian Tribe  
A. Bacock, Big Pine Paiute Tribe of  
the Owens Valley  
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(Chairman, Walker River Paiute Tribe)  
M. Bengochia, Bishop Paiute Indian Tribe  
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J. Leeds, Las Vegas Indian Center  
K. Tilges, Citizen Alert  
J. Triechel, Nuclear Waste Task Force  
W. Boyle, YMPO

E. Smith, Chemehuevi Indian Tribe  
J. Charles, Ely Shoshone Tribe  
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D. Eddy, Jr. Colorado River Indian Tribes  
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## **NRC Review of DOE Documents Pertaining to Key Technical Issue Agreements**

The U.S. Nuclear Regulatory Commission (NRC) goal of issue resolution during the pre-licensing period is to assure that the U.S. Department of Energy (DOE) has assembled enough information on a given issue for NRC to accept a license application for review. Resolution by the NRC staff during pre-licensing does not prevent anyone from raising any issue for NRC consideration during the licensing proceedings. Also, and just as important, resolution by the NRC staff during pre-licensing does not prejudge what the NRC staff evaluation of that issue will be after its licensing review. Issues are resolved by the NRC staff during pre-licensing when the staff has no further questions or comments about how DOE is addressing an issue. Pertinent new information could raise new questions or comments on a previously resolved issue.

This enclosure addresses five NRC/DOE agreements made during the August 6-10, 2001, Total System Performance Assessment and Integration (TSPAI) Technical Exchange and Management Meeting (see NRC letter dated August 23, 2001, which summarized the meeting) and four parts of one NRC/DOE agreement made during the September 18-19, 2001, Range of Thermal Operating Temperatures Technical Exchange and Management Meeting (see NRC letter dated October 2, 2001, which summarized the meeting). By letter dated May 9, 2002, DOE submitted information to address TSPAI Agreements 3.38, 3.39, 3.40, 3.41, 4.01, and four elements of General Agreement 1.01 (Items 56, 78, 96, and 120). The information was provided in a document entitled "Guidelines for Developing and Documenting Alternative Conceptual Models, Model Abstractions, and Parameter Uncertainty in the Total System Performance Assessment for the License Application" (herein referred to as the "Guidelines"). TSPAI Agreements 3.39, 3.40, and 4.01 involve information that is not included in the Guidelines. In its May 9, 2002, letter, DOE requested that NRC consider TSPAI Agreements 3.39, 3.40, and 4.01 as complete based on the approach outlined in the Guidelines. The document submitted and the associated Key Technical Issue (KTI) agreements are discussed below:

### **1) Total System Performance Assessment and Integration Agreement 3.38**

#### **Wording of TSPAI Agreement 3.38:**

DOE will develop guidance in the model abstraction process that can be adhered to by all model developers so that (1) the abstraction process, (2) the selection of conservatism in components, and (3) representation of uncertainty are systematic across the [Total System Performance Assessment] TSPA model. DOE will evaluate and define approaches to deal with: (1) evaluating non-linear models as to what their most conservative settings may be if conservatism is being used to address uncertainty, and (2) trying to utilize human intuition in a complex system. In addition, DOE will consider adding these items to the internal/external reviewer's checklists to ensure proper implementation of the improved methodology (TSPA0002).

DOE will develop written guidance in the model abstraction process for model developers so that (1) the abstraction process, (2) the selection of conservatism in components, and (3) representation of uncertainty, are systematic across the TSPA model. These guidelines will address: (1) evaluation of non-linear models when conservatism is being utilized to address uncertainty, and (2) utilization of decisions based on technical judgement in a complex system. These guidelines will be developed, implemented and be made available to the NRC in FY2002.

Enclosure

Wording of General Agreement 1.01 (Comment 78):

NRC Comment: Page 3-6<sup>1</sup>: “Uncertainties are addressed by bounding and sensitivity studies as discussed in DOE 2001...” Sensitivity studies can be an effective mechanism to assess uncertainties, however if the uncertainties show up as contributing to the output then they must be represented in the abstraction to the TSPA.

DOE Response: DOE acknowledges this concern, and will address specific, relevant issues according to KTI agreement TSPAI 3.38.

General Agreement 1.01 (Comment 78) references TSPAI Agreement 3.38 and, therefore, is included with this review.

NRC Review:

In its letter transmitting the Guidelines, DOE indicated that the guidance contained therein would supplement, in the level of detail, the governing procedure AP-SIII.10Q, *Models*. The Guidelines are written guidance that DOE developed for its model developers and provided to NRC to fulfill TSPAI Agreements 3.38, 3.39, 3.40, 3.41, and 4.01. The guidance addresses: (1) the abstraction process; (2) the selection of conservatism in components; and (3) the representation of uncertainty, including the use of alternative conceptual models. DOE has indicated that the Guidelines will be applied systematically across the TSPA model. In this respect, DOE has fulfilled the intent of TSPAI Agreement 3.38. The Guidelines acceptably describe DOE's approach to the abstraction process and the methodology for representation of uncertainty in a systematic fashion in the TSPA. When fully implemented, the Guidelines should result in greater transparency and consistency of various aspects of the model development and abstraction process.

The Guidelines do not fully address those aspects of TSPAI Agreement 3.38 designed to address the special considerations needed when relying on technical judgement in a complex system-model such as the TSPA (i.e., the evaluation of non-linear models when conservatism is being used and using decisions based on judgement in a complex system). It is acknowledged by the NRC staff that there will need to be instances where subjective information will be used in the TSPA. To the extent practical, these instances should be minimized. While the discussion on page 34 of the Guidelines mentions the items that the responsible individuals will consider in the model abstraction process, more detail is needed to make a decision about the acceptability of the approach (See #1, under Additional Information Needed).

The Guidelines only partially address Comment 78 of General Agreement 1.01. Although DOE has addressed the approach to documenting uncertainty, it has not implemented the approach and leaves open the decision on the appropriate methods to be used (e.g., see page 38 of the Guidelines).

Additional Information Needed:

1) DOE should provide a description of the approach used to evaluate the appropriateness of technical-judgment-based conservative selections, with respect to complex and non-linear models, and how the resulting decisions would be documented.

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<sup>1</sup> Supplemental Science and Performance Analyses Report

Status of Agreement: TSPAI Agreement 3.38 is listed as “need additional information.” Comment 78 of General Agreement 1.01 remains open.

## **2) Total System Performance Assessment and Integration Agreement 3.39**

### Wording of TSPAI Agreement 3.39:

In future performance assessments, DOE should document the simplifications used for abstractions per TSPAI.3.38 [TSPAI Agreement 3.38] activities. Justification will be provided to show that the simplifications appropriately represent the necessary processes and appropriately propagate process model uncertainties. Comparisons of output from process models to performance assessment abstractions will be provided, with the level of detail in the comparisons commensurate with any reduction in propagated uncertainty and the risk significance of the model (TSPA0003).

DOE will document the simplifications utilized for abstractions per TSPAI.3.38 activities for all future performance assessments. Justification will be provided to show that the simplifications appropriately represent the necessary processes and appropriately propagate process model uncertainties. Comparisons of output from process models to performance assessment abstractions will be provided, with the level of detail in the comparisons commensurate with any reduction in propagated uncertainty and the risk significance of the model. The documentation of the information will be provided in abstraction [Analysis/Model Reports] AMRs in FY 2003.

### NRC Review:

TSPAI Agreement 3.39 addresses the documentation that DOE should provide to allow the NRC staff to conduct a detailed review of the abstractions used in the TSPA that will support the potential license application. During the April 15-16, 2002, NRC/DOE Technical Exchange and Management Meeting on Key Technical Issue Agreements, DOE requested NRC to consider TSPAI Agreement 3.39 as complete based on the approach outlined in the Guidelines. DOE has indicated that the Guidelines provide the methodology that it intends to use when implementing the activities necessary to satisfy the agreement, and that the documentation, justification, and comparisons identified in the Guidelines would be provided later, in the appropriate model reports. The Guidelines describe the approach that DOE intends to use in the model abstraction process, including its approach to document the simplifications made during this process. The NRC staff has decided that it is premature to characterize TSPAI Agreement 3.39 as complete solely on the basis of the Guidelines provided by DOE. It is premature because: (1) there is no objective evidence of the successful implementation of the Guidelines and (2) the Guidelines do not embody the same gravity as do quality assurance procedural requirements, where audits are conducted to evaluate adherence to the procedures.

Additional Information Needed: The information requested in TSPAI Agreement 3.39 needs to be addressed.

Status of Agreement: TSPAI Agreement 3.39 is listed as “needs additional information.”



### **3) Total System Performance Assessment and Integration Agreement 3.40**

#### Wording of TSPAI Agreement 3.40:

DOE will implement effective controls to ensure that the abstractions defined in the AMR's are consistently propagated into the TSPA, or ensure that the TSPA documentation describes any differences. Specific examples of needed revisions (if still applicable) include: (1) the implementation of flux splitting in the TSPA model, (2) the propagation of thermohydrology uncertainty/variability into the WAPDEG corrosion model calculations, and (3) the implementation of the in-package chemistry abstraction.

DOE will implement program improvements to ensure that the abstractions defined in the AMRs are consistently propagated into the TSPA, or ensure that the TSPA documentation describes any differences. Program improvements may include, for example, upgrades to work plans, procedural upgrades, preparation of desktop guides, worker training, increased review and oversight. The program improvements will be implemented and be made available to the NRC during FY 2002.

#### NRC Review:

The intent behind TSPAI Agreement 3.40 was for DOE to develop controls on the model abstraction process that would lead to model abstractions in the TSPA that are consistent with the underlying process models and their limitations. In its letter transmitting the Guidelines, DOE indicated that the guidance contained therein would supplement, in the level of detail, the governing procedure AP-SIII.10Q, *Models*. As such, the Guidelines are intended to provide a consistent approach to the model abstraction process. The process for model abstraction in the Guidelines describes the involvement of subject matter experts and process modelers during the development of the abstraction and the documentation of the model abstraction. The process outlined by DOE provides an additional level of detail to that found in the governing procedure AP-SIII.10Q and is characterized as a program improvement. The program improvements outlined in the Guidelines address the NRC staff concerns and satisfy the intent of TSPAI Agreement 3.40.

Additional Information Needed: None

Status of Agreement: TSPAI Agreement 3.40 is listed as "complete."

### **4) Total System Performance Assessment and Integration Agreement 3.41**

#### Wording of TSPAI Agreement 3.41:

To provide support for the mathematical representation of data uncertainty in the TSPA, the DOE will provide technical basis for the data distributions used in the TSPA. An example of how this may be accomplished is the representation on a figure or chart of the data plotted as an empirical distribution and the probability distribution assigned to fit these data.

DOE will provide the technical basis for the data distributions utilized in the TSPA to provide support for the mathematical representation of data uncertainty in the TSPA. The documentation of the technical basis will be incorporated in documentation associated with TSPA for any potential license application. The documentation is expected to be available to NRC in FY 2003.

Wording of General Agreement 1.01 (Comment 120):

NRC Comment: Page 7-11<sup>2</sup>, The use of a triangular distribution for the residual stress uncertainty dictates that the endpoints of the distribution are well known. Showing the data compared to the distribution would support the selection of a triangular distribution.

DOE Response: A triangular distribution is used to represent uncertainty in the residual stress and stress intensity factor profiles in the weld regions of the outer and inner closure lids of the waste package Alloy 22 outer barrier. The triangular distribution was used because the uncertainty bounds are conservative, considering the strict process control and inspections that will be implemented during the waste package manufacturing process. If the data currently being obtained under existing CLST [Container Life and Source Term] KTI agreements 1.12 and 1.13 warrant a change in the assumed distribution, this would be carried forward into a potential TSPA-LA [total system performance assessment for license application] in accordance with KTI agreement TSPAI 3.41.

NRC Review:

TSPAI Agreement 3.41 addresses the documentation that DOE should provide to allow the NRC staff to conduct a detailed review of the abstractions used in the TSPA that will support the potential license application, specifically, a review of the mathematical representation of data uncertainty. The objective of the agreement was to ensure that documentation of parameter values would indicate clearly the basis for the distributions used in the performance assessment, so as to allow an evaluation of the degree of objectivity associated with the parameter value or distribution. During the April 15-16, 2002, NRC/DOE Technical Exchange and Management Meeting on Key Technical Issue Agreements, DOE requested NRC to consider TSPAI Agreement 3.41 as complete based on the approach outlined in the Guidelines. DOE has indicated that the Guidelines provide the methodology that it intends to use when implementing the activities necessary to satisfy the agreement and that the documentation of the technical bases for the data distributions would be provided later, in the appropriate model reports. The Guidelines describe the approach that DOE intends to use when developing and documenting these technical bases. The NRC staff has decided that it is premature to characterize TSPAI Agreement 3.41 as complete solely on the basis of the Guidelines provided by DOE. It is premature because: (1) there is no objective evidence of the successful implementation of the Guidelines and (2) the Guidelines do not embody the same gravity as do quality assurance procedural requirements, where audits are conducted to evaluate adherence to the procedures. In addition, the NRC staff has identified, based on the content of the Guidelines, additional information that is needed.

As described in the Guidelines, the reasoning (i.e., basis) for the distribution (shape and range) of the parameters used in the TSPA is to be documented. Providing this information would satisfy the intent behind Comment 120 of General Agreement 1.01. The NRC staff will continue to evaluate the response to Comment 120 of General Agreement 1.01 in conjunction with the more general TSPAI Agreement 3.41.

Approaches, such as the use of informational entropy (e.g., step 4 on page 49), may produce unbiased estimates of distributions based on limited data, but these distributions are always the

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<sup>2</sup> Supplemental Science and Performance Analyses Report

most inclusive and therefore widest. The NRC staff has shown by computational experiments that unduly wide distributions of some parameters, especially those that determine the timing of the individual peak doses, may lead to a lower peak of the expected dose. The same wide distributions would not necessarily lead to lower peak doses of the individual realizations. The resulting change, from using unduly wide distributions, to the peak expected dose within the first 10,000 years after closure, could be either an increase or a decrease in the calculated value. One of the conclusions that may be inferred from these results is that the informational entropy approach may be well-suited for calculating conservative values for individual peaks, but may not be as well-suited for dealing with the NRC criteria because its effect on the peak expected dose within the compliance period needs to be considered. Because information entropy may lead to wider distributions and lower dose estimates as a consequence of sparse data, the use of informational entropy should be discussed with respect to data sufficiency. (See #1, under Additional Information Needed.)

Both variability and uncertainty are discussed (e.g., page 29) in the Guidelines. DOE has not adequately documented how it intends to address scaling issues in its approach to treating variability. It is unclear how DOE will address the uncertainty associated with the lumping, or smoothing, of variability. (See #2, under Additional Information Needed.)

As part of the documentation for the selected range and shape of parameter distributions, the use of unqualified data should be made clear. Specifically, it should be clear whether the unqualified data are used to corroborate qualified data or to inform an opinion on the range and/or shape of the parameter distribution. For example, say parameter X has two measured values, 2 and 3, and the analyst decides, in order to represent uncertainty, that they are going to represent the distribution as uniform from 0 to 5. The analyst has unqualified data from other sources (such as published journals), to suggest the values should be between 0 and 5. The unqualified data should be characterized as supporting the assumption for the uncertainty in parameter X, otherwise the unqualified data are being used to define the uncertainty in parameter X. Additionally, there are formal methods for using “soft” (e.g., indirect) data alongside hard (qualified direct) data; e.g., “Fuzzy sets” and “Soft Kriging.”

The development of a TSPA parameter database that will be linked with the GoldSim software — which is used to develop the TSPA model — during TSPA analyses should greatly facilitate DOE’s efforts to improve transparency and traceability in its TSPA analyses. In addition, the use of this database should facilitate the consistent use of data (and uncertainty) within the TSPA model. While not explicitly covered in the original agreement, DOE should consider using a hierarchical parameter database, within main process-model topical areas and/or throughout the whole project, that would facilitate tracing data from its source to its disposition within the TSPA, or vice versa.

Additional Information Needed: In addition to the information that DOE has already acknowledged that it needs to provide in response to this agreement (i.e., documentation, justification, and comparisons that are to be provided in the model reports), the following information is needed from DOE.

- 1) Justification that the DOE’s use of the information entropy approach is appropriate, when used to develop the expected annual dose to the reasonably maximally exposed individual and demonstration of compliance with the groundwater concentration limits should be provided.
- 2) The approach that DOE will use to address variability, specifically, the lumping (smoothing) of variability, when parameters are defined, should be provided.

Status of Agreement: TSPAI Agreement 3.41 is listed as “need additional information.”  
Comment 120 of General Agreement 1.01 remains open.

5) Total System Performance Assessment and Integration Agreement 4.01

Wording of TSPAI Agreement 4.01:

DOE will document the methodology that will be used to incorporate alternative conceptual models into the performance assessment. The methodology will ensure that the representation of alternative conceptual models in the TSPA does not result in an underestimation of risk. DOE will document the guidance given to process-level experts for the treatment of alternative models. The implementation of the methodology will be sufficient to allow a clear understanding of the potential effect of alternative conceptual models and their associated uncertainties on the performance assessment. The methodology will be documented in the TSPA-LA methods and assumptions document in FY02. The results will be documented in the appropriate AMRs or the TSPA for any potential license application in FY 2003.

Wording of General Agreement 1.01 (Comments 56 and 96)

NRC Comment #56 Page 2-1<sup>3</sup>: *‘There are also cases where more than one conceptual model may be consistent with available data and observations. In the absence of definitive data or compelling technical arguments for a specific conceptual, process, or abstracted model, a conservative representation was chosen.’* It is unclear what the criteria were to determine when a conservative selection was necessary. In the saturated zone modeling, there is evidence to suggest anisotropy and isotropic conditions. These states were equally weighted in the TSPA model which is inconsistent with the language highlighted above. Clarification of the DOE position on alternative conceptual models needed.

DOE Response: The statement is generally true across inputs to the performance assessment. In most cases, the implications of alternative conceptual models are evaluated using “one-off” sensitivity analyses, presented in Section 3 of Volume 2 of the SSPA. In a few cases, alternative conceptual models are propagated through the performance assessment. Note that Agreement TSPAI 4.01 covers treatment of alternative conceptual models. Alternative conceptual models are screened out during the process model calibration. Sensitivity analyses are completed to investigate the effects of alternative models on the SZ [saturated zone] flow field, specific discharge and radionuclides transport. In addition, alternative conceptual models are documented in the SZ PMR [process model report] and its revisions.

NRC Comment #96 Page 4-56<sup>4</sup>: The analytical work is an excellent example of alternative methods that can be pursued as multiple lines of evidence. However, in this case it does raise additional technical questions. For example, would the chemistry of the solution in the above boiling region influence the behavior? In particular, if the solution were a chloride-brine would it have

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<sup>3</sup> Supplemental Science and Performance Analyses report

<sup>4</sup> Supplemental Science and Performance Analyses report.

different physical characteristics than dilute water? Secondly, if 15% of the realizations predicted penetration, then roughly 1600+ waste packages (on average) should experience these conditions. Finally, where is the support for the original modeling result if the analytical result contradicts the conclusions made with the original model? Page 4-57 [of the Supplemental Science and Performance Analyses report] describes “more extreme conditions”, but it was not obvious that the conditions were more extreme in the analytical work, rather it appeared that the analytical work evaluated processes on a scale that the numerical model can not evaluate.

DOE Response: Although the asperity-induced episodic infiltration model provides convenient analytical expressions for the episodicity and water-penetration distances, it also includes a number of important assumptions (consistent with KTI agreement TSPAI 4.01)...

NRC Review:

TSPAI Agreement 4.01 includes two types of information. The first is the methodology that DOE would use to incorporate alternative conceptual models into the performance assessment. The second is the documentation of the appropriate information relating to the consideration of alternative conceptual models. The Guidelines document the DOE approach for considering alternative conceptual models and propagating model uncertainty, including the representation of alternative conceptual models in the performance assessment. During the April 15-16, 2002, NRC/DOE Technical Exchange and Management Meeting on Key Technical Issue Agreements, DOE requested NRC to consider TSPAI Agreement 4.01 as complete based on the approach outlined in the Guidelines. The NRC staff has decided that it is premature to characterize TSPAI Agreement 4.01 as complete solely on the basis of the Guidelines provided by DOE. It is premature because: (1) there is no objective evidence of the successful implementation of the Guidelines and (2) the Guidelines do not embody the same gravity as do quality assurance procedural requirements, where audits are conducted to evaluate adherence to the procedures. In addition, the NRC staff has identified additional information that is needed to allow the NRC staff to conduct a detailed review of the potential license application.

The Guidelines do provide clarification of the DOE position on alternative conceptual models, which addresses comment 56 of General Agreement 1.01. The Guidelines do not address comment 96 of General Agreement 1.01. Comment 96 of General Agreement 1.01 will continue to be considered when evaluating DOE's progress on providing the information requested by TSPAI Agreement 4.01.

DOE has identified three criteria for judging whether it is appropriate to consider alternative conceptual models. One criterion is that the alternative model is reasonable. DOE has used a statement in Regulatory Guide 1.174, “An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis,” as a criterion to determine whether, or not, an alternative conceptual model needs to be considered. The restrictive statement excerpted from Regulatory Guide 1.174 includes the following: “reasonable is interpreted as implying some precedent for the alternative, such as use by other analysts.” It is not clear that it is appropriate to limit consideration of alternative conceptual models to those that have already been used by other analysts, particularly given the absence of similar facilities (which could provide a useful precedent) and the site- and design-specific models that would be appropriate for a repository located in the unsaturated zone at Yucca Mountain, Nevada. (See #1, under Additional Information Needed.)

Another criterion is that the alternative conceptual model is consistent with available data and current scientific understanding. It appears, based on the text on page 16 of the Guidelines, that DOE intends this consistency criterion to mean that a given model may need to be "consistent with all information" (emphasis added) to be considered. It is unlikely that any conceptual model will be found to be consistent with "all" data or information. Therefore DOE's approach to using its consistency criterion needs to be clarified. (See #2, under Additional Information Needed.)

The Guidelines indicate (page 17) that, for a given alternative conceptual model, the subject matter expert will develop and provide a confidence distribution for use in weighting its alternatives, using the approach in NUREG-1563, "Branch Technical Position on the Use of Expert Elicitation in the High-Level Radioactive Waste Program;" the Branch Technical Position describes an acceptable approach to formally elicit expert judgment and where formal elicitation may be appropriate. Expert elicitation is not required to be used to develop weights for alternative conceptual models. Although it is not required, it may be appropriate to use formal expert elicitation when assigning weights to alternative conceptual models, such as when the alternatives lead to significantly different results and, consequently, the weighting has a potentially significant effect on the calculated performance of the repository. The level of support that DOE uses to justify its weighting of alternative conceptual models should be no less than that which is commensurate with the importance of that portion of the repository system to performance. The basis and judgments used to develop weights for alternative conceptual models should be fully documented. The documentation should include appropriate disclosure, such as whether the technical expert assigning the weights was directly involved in the development of the models. It is not clear how DOE will convey the uncertainty associated with particular alternative conceptual models. (See #3, under Additional Information Needed.)

DOE may consider alternative conceptual models at any stage in the performance assessment and does not need to carry each alternative to the total system performance assessment model. DOE will need to address the implications of the viable alternative conceptual models for their estimates of repository performance (model uncertainty). If DOE weights alternative conceptual models, then DOE should develop and provide an appropriate amount of information to allow the effects of the alternative conceptual models and DOE's weighting to be understood. DOE does not need to present the dis-aggregated consequences of each combination of alternative models. DOE should consider presenting the estimated performance of the repository (dis-aggregated results) for those combinations that are reasonably important or potentially significant and other appropriate documentation that pertains to those combinations of alternative conceptual models. (See #3, under Additional Information Needed.)

DOE has not documented clearly how its approach to propagating model uncertainty will ensure that the representation of alternative conceptual models will not result in an underestimate of the risk, because the Guidelines do not address this point. (See #4, under Additional Information Needed.) In light of the uncertainty that will be present, some of which may be irreducible, the NRC staff does not expect DOE to show that the estimates resulting from the DOE approach are not lower than the "true risk." Rather, the approach used should not represent the risk as less than the best estimate of risk, based on the scientific understanding of the relevant processes and reasonably attainable data (See #4, under Additional Information Needed) or make the contributions of particular conceptual models inscrutable (See #3, under Additional Information Needed). In addition, it is unclear how DOE will convey the effect that uncertainty in model confidence (i.e., uncertainty on the weights assigned to the different models) would have on the results. (See #3, under Additional Information Needed.)

The Guidelines indicate (e.g., page 16) that alternative conceptual models will be developed only for areas with sensitive or key parameters. The Guidelines indicate later that this will be

based upon system-level performance. Sensitive or key parameters could change with the set of alternative conceptual models being used, or with changes to a preferred model. Models which exhibit greater variability than the preferred model might affect the representation of the uncertainty in the results and the relative importance of other model abstractions (or parameters). (See #5, under Additional Information Needed.)

Using the traditional definition of validation, conceptual models with “significantly different” behavior cannot both be validated. The extent to which the behavior of alternative conceptual models may differ is influenced by the validation criteria that are used. In the Guidelines, the validation criteria are developed by the subject matter experts. This could result in an inconsistent consideration of alternative conceptual models, so the representation of uncertainty may not be systematic throughout the performance assessment. (See #6, under Additional Information Needed.)

Additional Information Needed: In addition to the information that DOE has already acknowledged that it needs to provide in response to this agreement (i.e., the documentation that is to be provided in the respective model reports), the following information is needed from DOE.

- 1) Clarification of DOE’s use of reasonableness (see, for example, page 13 of the Guidelines) and/or additional justification for the criteria that alternative conceptual model must be “reasonable” as used in Regulatory Guide 1.174, “An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis,” should be provided.
- 2) Clarification of how DOE intends to apply its criterion on consistency with available data and scientific understanding. If the absence of validation information (e.g., data) is used to reject an alternative conceptual model, this approach and subsequent decisions where this is done should be documented and justified.
- 3) Clarification of DOE’s approach to documenting the effects of alternative conceptual models and how it will be sufficient to allow a clear understanding of the potential effects of alternative conceptual models and their uncertainty on the performance assessment. This clarification should include DOE’s approach to presenting dis-aggregated results of alternative conceptual models.
- 4) Clarification of how DOE’s approach — which, according to the Guidelines, involves weighting alternative conceptual models — will avoid underestimating the risk when the results are presented.
- 5) Clarification of its approach to using sensitive or key parameters from previous analyses when evaluating potential future alternative conceptual models. If DOE intends to use a threshold for discriminating these parameters from others, this should be expressed.
- 6) Clarification of the guidance that will be given to the model developers that would provide consistency in the development of model validation criteria, such that the representation of uncertainty is systematic throughout the performance assessment.

Status of Agreement: TSPAI Agreement 4.01 is listed as “need additional information.” Comment 56 of General Agreement 1.01 is listed as complete. Comment 96 of General Agreement 1.01 remains open.